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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,020	10/20/2003	Robert Kisilevsky	NCI-043CN2	4006

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,020	KISILEVSKY ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The disclosure is objected to because of the following informalities: The status of the parent non-provisional applications in the claim for priority at page 1, lines 4-5, of the specification should be updated. Appropriate correction is required.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,310,073. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '073 patent anticipate instant claim 1.

4. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,670,399. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '399 patent anticipate instant claim 1. Cerebral amyloid angiopathy is a condition which inherently involves a glycosaminoglycan-associated molecular interaction. Because the same active agent is administered to the same subject by the same method steps, inherently a glycosaminoglycan-associated molecular interaction will be modulated in the claimed method of the '399 patent to the same extent claimed by Applicants.

5. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/654,863. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '863 application anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Instant claim 1 is deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/094,454 because the '454 application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 90/08541. The WO Patent Application '541 teaches treating metastatic adrenocortical cancer by administering suramin, which inhibits the molecular interaction between lysosomal enzymes and glycosaminoglycans. Suramin comprises plural sulfonate groups attached to an aromatic carrier. The suramin can be administered in combination with a pharmaceutically acceptable carrier. See, e.g., the Abstract; page 1, lines 4-12; and page 22, lines 18-30. Note that Applicants have defined aromatic groups at page 16, lines 18-19, of their specification as embracing substituted aromatic groups.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kisilevsky et al (U.S. Patent No. 5,643,562). Kisilevsky et al '562 teach inhibiting amyloid deposition by administering compounds which inhibit the molecular interaction between amyloidogenic protein and glycosaminoglycans. The compounds are the same as those claimed by Applicants, e.g., the compounds can be aliphatic-based such as 1,3-propanedisulfonic acid. The compounds can be administered in combination with a pharmaceutically acceptable vehicle. Amyloid deposition is defined to include bovine spongiform encephalitis and other prion protein-based diseases. See, e.g., the Abstract; column 1, lines 33-37; column 3, lines 44-56; the Examples; and claims 1-55.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cardin et al (U.S. Patent No. 5,494,932). Cardin et al teach treating HIV, CMV, and HSV infections by administering compounds comprising two sulfonic acid groups. The compounds are administered in combination with pharmaceutically acceptable carriers. See, e.g., column 4, lines 61-65; column 7, line 37 - column 8, line 46; and claims 1-4. The carrier portion of Cardin et al's compounds is comprises an aromatic group and an aliphatic group. Note that Applicants have defined aliphatic groups at page 15, lines 6-7, of their specification as embracing substituted aliphatic groups and have defined aromatic groups at page 16, lines 18-19, of their specification as embracing substituted aromatic groups. Cardin et al's compounds have the same structure required by the formula recited in Applicants' claims. Because the same viral infections are being treated in the same subject with a compound having the same structural formula in both Cardin et al and Applicants' claimed invention, inherently a glycosaminoglycan-associated molecular interaction will be modulated in the method of Cardin et al to the same

extent claimed by Applicants. Note that patentability can not be based merely upon the employment of descriptive language not chosen by the prior art (In re Skoner, 186 USPQ 80, 82 (CCPA 1975)), and can not be based merely upon the provision of a fuller scientific explanation of what inherently occurs in a prior art method (In re King, 231 USPQ 136, 139 (CAFC 1986)).

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Umezawa et al (U.S. Patent No. 4,091,202). Umezawa et al teach treating S. aureus and P. aeruginosa infections by administering 3',4'-dideoxykanamycin B derivatized with N-methanesulfonic acid groups. The compounds are administered in combination with pharmaceutically acceptable carriers. See, e.g., column 2, line 10 - column 3, line 3; Table 1; and column 5, lines 17-53. The methane group in the N-methanesulfonic acid group of Umezawa et al's compounds is deemed to constitute an aliphatic group. Note that Applicants have defined aliphatic groups at page 15, lines 6-7, of their specification as embracing substituted aliphatic groups. Umezawa et al's compounds have the same structure required by the formula recited in Applicants' claim. Because the same active agent is being administered to the same subject in Umezawa et al as in the instant claimed method, inherently a glycosaminoglycan-associated molecular interaction will be modulated in Umezawa et al to the same extent claimed in the instant claim. Sufficient evidence of similarity is deemed to be present between Umezawa et al and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of Umezawa et al.

12. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by the West Derwent Abstract. The West Derwent Abstract teaches an aerosol form of a compound having chlamydostatic action. The compound comprises a methanesulphonic acid group. The methane

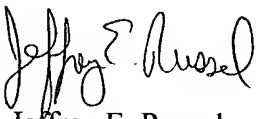
group in the N-methanesulfonic acid group of the West Derwent Abstract's compound is deemed to constitute an aliphatic group. Note that Applicants have defined aliphatic groups at page 15, lines 6-7, of their specification as embracing substituted aliphatic groups. The West Derwent abstract's compound has the same structure required by the formula recited in Applicants' claim. Because the same active agent is being administered to the same subject in the West Derwent Abstract as in the instant claimed method, inherently a glycosaminoglycan-associated molecular interaction will be modulated in the West Derwent Abstract to the same extent claimed in the instant claim. Sufficient evidence of similarity is deemed to be present between the West Derwent Abstract and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of the West Derwent Abstract.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by the Helgstrand et al article (Current Chemotherapy & Infectious Dis., Vol. 2, pages 1359-1361). The Helgstrand et al article teaches in vivo administration of trisodium phosphonoformate (i.e. foscarnet sodium) to guinea pig infected with HSV. See, e.g., page 1359, column 1. Because the same active agent is being administered to the same subject in the Helgstrand et al article as in the instant claimed method, inherently a glycosaminoglycan-associated molecular interaction will be modulated in the Helgstrand et al article to the same extent claimed in the instant claim. Sufficient evidence of similarity is deemed to be present between the Helgstrand et al article and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of the Helgstrand et al article.

14. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gulliya et al (U.S. Patent No. 5,091,385). Gulliya et al teach pre-activated merocyanine 540, which comprises a sulfopropyl group, for use in treating infections by viruses such as herpes simplex virus, cytomegalovirus, and HIV. The active agent is mixed with a pharmaceutically acceptable carrier or vehicle. See, e.g., column 1, lines 7-14; column 10, liens 4-48; column 11, lines 52 and 57-59; column 12, lines 13-15; and Table 14. Gulliya et al's compounds have the same structure required by the formula recited in Applicants' claim. Because the same viral infections are being treated in the same subject with a compound having the same structural formula in both Gulliya et al and Applicants' claimed invention, inherently a glycosaminoglycan-associated molecular interaction will be modulated in the method of Gulliya et al to the same extent claimed by Applicants. Note that patentability can not be based merely upon the employment of descriptive language not chosen by the prior art (In re Skoner, 186 USPQ 80, 82 (CCPA 1975)), and can not be based merely upon the provision of a fuller scientific explanation of what inherently occurs in a prior art method (In re King, 231 USPQ 136, 139 (CAFC 1986)). Sufficient evidence of similarity is deemed to be present between Gulliya et al and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of Gulliya et al.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

November 30, 2004